DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

December 15, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 – 05

Daniel W. Nolan
Owner
Nolan Livestock
407 East Park Street
Bonduel, Wisconsin 54107

Dear Mr. Nolan:

On July 12 and 21, 2004, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your operation located in Bonduel, WI. That inspection confirmed that you offered an animal for sale for slaughter as food that was adulterated under Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You also caused the adulteration of a new animal drug per Section 501(a)(5) of the Act because the drug was used in a manner that does not conform with its approved use or extralabel use regulations, therefore making it unsafe within the meaning of Section 512 of the Act.

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On or about January 15, 2004, you sold a dairy cow, identified with back tag number [redacted] for slaughter as human food to [redacted] United States Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 127.85 parts per million (ppm) gentamicin in the kidney, 2.43 ppm in the liver, and 2.35 ppm in muscle. No tolerance has been established for residues of gentamicin in the edible tissues of dairy cows (21 CFR 556.300). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." Our investigation found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. For example, you do not maintain medication records to avoid unsafe residues. You also lack an adequate system for assuring that drugs are not used in a manner contrary to the labeled directions and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

In addition, you caused the adulteration of gentamicin within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the approved conditions of use or the extralabel use regulations at 21 CFR Part 530. A copy of these regulations is enclosed. Gentamicin is not approved for use in dairy cattle. Extralabel use is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in conformance with the criteria set forth in 21 CFR Part 530.

A veterinarian prescribed gentamicin for extralabel use to treat shipping fever in calves housed at the same facility where you house cattle prior to sale. Because your use of gentamicin in a dairy cow was not on the order of a licensed veterinarian, use was not in compliance with extralabel use regulations (21 CFR 530.10, 530.11(a)). In addition, use of the drug did not comply with 21 CFR 530.11(c) because the use resulted in a residue which may present a risk to the public health. As a result, your use of this drug caused it to be adulterated within the meaning of Section 501(a)(5) of the Act and unsafe within the meaning of Section 512 of the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action, such as seizure and/or injunction, without further notice.

The violations discussed above are not intended to be an all-inclusive list of violations. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you frequently are the individual who introduces or offers for introduction into interstate commerce the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug, and Cosmetic Act. To avoid future illegal residue violations, you should take precautions such as:

1. Implementing a recordkeeping system that includes information on the source of the animals you purchase or lease;

2. Implementing a recordkeeping system to determine whether animals you purchase or lease have been medicated, when they were medicated, and with what drug(s); and

3. Implementing a system to ensure that withdrawal periods prior to slaughter are met for medicated animals.

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Brian D. Garthwaite, Ph.D. at the address indicated on the letterhead.

Sincerely,

Annette Byrne for

W. Charles Becoat
Director
Minneapolis District

BDG/ccl

Enclosure: 21 CFR 530